

JUL - 9 2009

K091941

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: \_\_\_\_\_.

### 1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD  
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen,  
518057, P. R. China

Tel: +86 755 2658 2888

Fax: +86 755 2658 2680

### Contact Person:

Tan Chuanbin

Shenzhen Mindray Bio-medical Electronics Co., LTD  
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,  
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: May 26, 2009

### 2. Device Name: DC-3/DC-3T Diagnostic Ultrasound System

#### **Classification**

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

### 3. Marketed Device:

The subject device is substantially equivalent in its technologies and functionality to the original DC-3/DC-3T Diagnostic Ultrasound System that is already cleared under premarket notification number K083505, and the other predicate devices are listed below: Mindray M5 (K080640), Mindray DC-6 (K072164), GE Voluson 730 (K041688).

#### **4. Device Description:**

The DC-3/DC-3T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

#### **5. Intended Use:**

The device is intended for use by a qualified physician for ultrasound evaluation of gynecology, obstetrics, abdominal, pediatric, small parts (breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac transvaginal, transrectal, peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

#### **6. Safety Considerations:**

The DC-3/DC-3T Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard: 2004. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

#### **Conclusion:**

The conclusions drawn from testing of the DC-3/DC-3T Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
% Mr. Robert Mosenkis  
President  
CITECH  
5200 Butler Pike  
Plymouth Meeting, PA 19462-1298

Re: K091941  
Trade/Device Name: DC-3/DC-3T Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYO, IYN, and ITX  
Dated: June 24, 2009  
Received: June 30, 2009

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-3/DC-3T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5A  
6CV1  
7L4A  
7L6  
10L4  
6C2  
6LE7

6LB7  
3C1  
2P2  
7L5  
7LT4  
D6-2

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

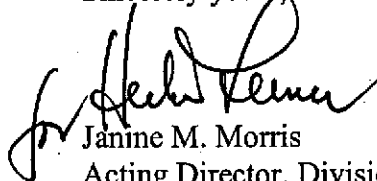
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

### Diagnostic Ultrasound Indications for Use Form

System X Transducer DC-3/DC-3T  
 Model: \_\_\_\_\_  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 3, 4, 5
Abdominal	P	P	P	P	P	P	P	Note 1, 2, 3, 4, 5
Intraoperative (specify)*	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P	P	P	P	P	Note 1, 2, 3, 4, 5
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2, 3, 4
Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2, 3
Trans-rectal	P	P	P		P	P	P	Note 2, 3, 4
Trans-vaginal	P	P	P		P	P	P	Note 2, 3
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								
Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2, 3
Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2, 3
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***	P	P	P		P	P	P	Note 1, 2, 3, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

Note 5: 4D

(Division Sign-Off)

Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number

K091941

0085

### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: 3C5A  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 3
Abdominal	P	P	P		P	P	P	Note 1, 2, 3
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 3
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1, 2, 3
Other (specify)***	P	P	P		P	P	P	Note 1, 2, 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

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### Diagnostic Ultrasound Indications for Use Form

System

Transducer

X

Model:

6CVI

510(k) Number(s)

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 2, 3
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note 2, 3
Trans-vaginal	P	P	P		P	P	P	Note 2, 3
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P	P		P	P	P	Note 2, 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

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510(k) Number

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### Diagnostic Ultrasound Indications for Use Form

System

Transducer

X

Model:

7L4A

510(k) Number(s)

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

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### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_ 7L6  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								Note 2, 3, 4
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

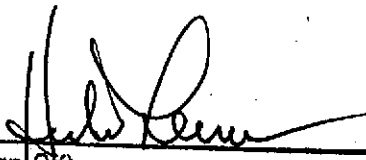
\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

  
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### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_ 10L4  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								Note 2, 3, 4
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								Note 2, 3, 4
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

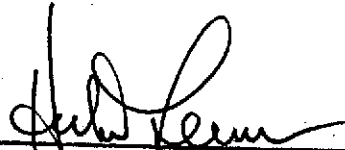
\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

  
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Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number K091941

### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_ 6C2  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3
Small organ(specify)**								
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3
Adult Cephalic	P	P	P		P	P	P	Note 2, 3
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P	P		P	P	P	Note 2, 3
Cardiac Pediatric	P	P	P		P	P	P	Note 2, 3
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P	P		P	P	P	Note 2, 3

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

  
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Division of Reproductive, Abdominal and  
 Radiological Devices

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### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_  
 510(k) Number(s) 6LE7

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 2, 3, 4
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note 2, 3, 4
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P	P		P	P	P	Note 2, 3, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

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Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number

4091941

0092

### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: 6LB7  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note 2, 3, 4
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P	P		P	P	P	Note 2, 3, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.


\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

  
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Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number K091941

**Diagnostic Ultrasound Indications for Use Form**

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_ 3C1  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 3
Abdominal	P	P	P		P	P	P	Note 1, 2, 3
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 3
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P	P		P	P	P	Note 1, 2, 3
Cardiac Pediatric	P	P	P		P	P	P	Note 1, 2, 3
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

(Division Sign-Off)

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 Radiological Devices

510(k) Number

*Handwritten signature*  
 K0919418

### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: \_\_\_\_\_ 2P2  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P	P	P	P	P	Note 1, 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P	P	P	P	P	Note 1, 2
Small organ(specify)**								
Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2
Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2
Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

(Division Sign-Off)

Division of Reproductive, Abdominal and  
 Radiological Devices

510(k) Number

K091941

0095

## Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: 7L5  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

(Division Sign-Off)

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510(k) Number

K091941

0096



### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X  
 Model: 7LT4  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (specify)*	P	P	P		P	P	P	Note 2, 3, 4
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Beam

(Division Sign Off)

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510(k) Number

K091941

0097

### Diagnostic Ultrasound Indications for Use Form

System \_\_\_\_\_ Transducer X \_\_\_\_\_  
 Model: D6-2  
 510(k) Number(s) \_\_\_\_\_

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2, 3, 5
Abdominal	N	N	N		N	N	N	Note 1, 2, 3, 5
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1, 2, 3, 5
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

\*Intraoperative includes abdominal, thoracic, and vascular etc.

\*\*Small organ-breast, thyroid, testes, etc.

\*\*\*Other use includes Urology.

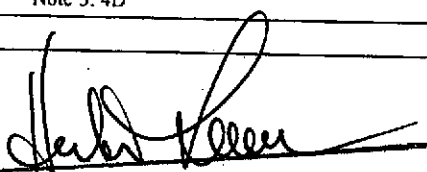
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: iBeam

Note 5: 4D

  
 (Division Sign-off)  
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 510(k) Number K091941